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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,150	04/27/2001	Pierre Chambon	065691/0219	7311

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FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/843,150

Applicant(s)

CHAMBON, ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**P riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24, 26-46 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) 26-46 and 49-52 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-24 and 53 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Receipt is acknowledged of an amendment filed 3/3/2003 as Paper No. 10. Receipt is also acknowledged of a supplemental response, filed 6/19/03 as Paper No. 13, in which a corrected version of the marked-up copy of the amended claims was submitted. In Paper No. 10, several claims were amended (claims 1, 5-12, 16 and 17) and a new claim added (claim 53). Claims 1-24, 26-46 and 49-53 are pending in the instant application, with claims 26-46 and 49-52 withdrawn from consideration as being directed to nonelected inventions.

#### ***Response to Amendment***

Any rejection of record in the previous office action, Paper No. 9 mailed 12/03/02, not addressed herein is withdrawn. This action is not final due to additional new rejections made herein that were not necessitated by applicants' amendment of the claims in Paper No. 10.

#### ***Information Disclosure Statement***

Receipt is acknowledged of an Information Disclosure Statement filed 3/28/03 as Paper No. 11. The signed and initialed PTO Form 1449 has been mailed along with this action.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wild et al (applicants' submission A6; Gene 1998, Vol. 223, pages 55-66; see the entire document).

**This is a new rejection.**

Wild et al teach the retrofitting of pre-existing libraries of transposon insertions with FRT and oriV elements in order to use the retrofitted constructs for generation of large quantities of genomic DNA fragments (e.g. the Abstract). In Figure 7, Wild et al demonstrate the generation of isolated DNAs comprising recombination sequences in the order of Lox-FRT-Lox-FRT where the Lox sequences are in opposite orientation with one another and the FRT sequences are in opposite orientation with one another (e.g. Figure 7A). In this example the Lox sequences flank, at least, the first FRT sequence, and the FRT sequences flank the second Lox sequence as well as genomic sequences.

It appears that the Lox-FRT-Lox cassette present in the pMS10.1 and pMS10.2 vectors used to generate the recombinant molecules described in Figure 7 comprise additional sequences between the two Lox sites and the FRT site (e.g. see Figure 3; sequences include, at least, oriV, MCS2 and a BamHI restriction site). Therefore, the limitations of claims 2 & 4 have been met.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

### *Claim Objections*

Claim 13 is objected to because of the following informalities: it is improper to use the term "composed of" delineating the members of a Markush group. It would be remedial to delete the term and replace it with the words "consisting of". Appropriate correction is required.

Claim 15 is objected to because it also comprises improper Markush group language and should be amended to read something like "selected from the group consisting of A, B and C".

Claim 18 is objected to because of the following informalities: the words "are coding for" are grammatically incorrect and should be changed to read "encode".

Claim 23 is objected to because of the following informalities: the word "acaline" is misspelled. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "sequences L1 (or L2) are in an orientation opposite to one another" are unclear. It is unclear whether the phrase is meant to encompass embodiments where the recombination sites are in an orientation where they point to one another, point away from one another, or both. It would be

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remedial to amend the claim language to clearly indicate which of the three possibilities is encompassed by the cited phrase.

Claim 14 is vague and indefinite in that the claim recites the DNA molecule of claim 1, but insists that it comprises additional sequences outside of the limits of the DNA molecule of claim 1. Thus, claim 14 does not further limit claim 1, upon which it is dependent. It would be remedial to amend the claim to clearly indicate what components of claim 1 are flanked by the additional SSRTS sites or to write a new claim directed to an isolated nucleic acid comprising the isolated DNA of claim 1 further flanked by additional SSRTS.

Claim 17 is vague and indefinite in that the metes and bounds of the term "protein of interest" are unclear. The term is highly subjective and subject to interpretation by the individual investigator. It would be remedial to amend the claim language to clearly indicate what is intended by the words "protein of interest".

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD  
Examiner  
Art Unit 1636

Ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER